DAIDS
Bethesda, MD, USA

Appendix

Reporting Critical Events to DAIDS

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Reporting Critical Events to DAIDS

To fulfill the regulatory requirements for reporting certain critical events, the Division of AIDS (DAIDS) would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in a report submitted to DAIDS:

For unanticipated problems involving risks to participants or others:
Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;

a. Title of the research project and/or grant, contract or cooperative agreement in which the problem occurred;
b. Name of the principal investigator (PI) on the protocol;
c. Number of the research project assigned by the Institutional Review Board (IRB)/Ethics Board (EC) and the number of any applicable National Institute of Allergy and Infectious Diseases (NIAID) (DAIDS) award(s) (grant, contract, or cooperative agreement);
d. A detailed description of the problem; and
e. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants, etc.).

For serious or continuing noncompliance:

a. Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
b. Title of the research project and/or grant, contract or cooperative agreement in which the noncompliance occurred, or, for IRB/EC or institutional noncompliance, the IRB/EC or institution involved;
c. Name of the PI on the protocol;
d. Number of the research project assigned by the IRB/EC and the number of any applicable NIAID (DAIDS) award(s) (grant, contract, or cooperative agreement);
e. A detailed description of the noncompliance; and
f. Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB/EC or institutional official, develop or revise IRB/EC written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

For suspension or termination of IRB/EC approval:

a. Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
b. Title of the research project and/or grant, contract or cooperative agreement that was suspended or terminated;
c. Name of the PI on the protocol;
d. Number of the research project assigned by the IRB/EC that was suspended or terminated and the number of any applicable NIAID (DAIDS) award(s) (grant, contract, or cooperative agreement);
e. A detailed description of the reason for the suspension or termination; and
f. The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)